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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/607,246

06/25/2003

George Baran

6298/432

4973

7590

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EXAMINER

DEMILLE, DANTON D

ART UNIT

PAPER NUMBER

3771

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/607,246	<b>Applicant(s)</b> BARAN, GEORGE	
	<b>Examiner</b> Danton DeMille	<b>Art Unit</b> 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 69-74, 81-97, 99-103 and 106-119 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 91-97 and 109-119 is/are allowed.
- 6) ☒ Claim(s) 69-74, 99, 101, 102, 106 and 107 is/are rejected.
- 7) ☒ Claim(s) 81-90, 100, 103 and 108 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/9/2008</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 103***

**Claims 69-74 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Smith et al. '613.**

Smith discloses, for example, a catheter 4 for delivering an aerosol of medicine to a patient comprising: a catheter shaft 4 having a proximal end and a distal end 38. A lumen 2 extending through the catheter shaft and adapted at a proximal end for receiving a medicine and communicating at the distal end 8 with a distal medicine orifice 10 from which the medicine is discharged in a direction toward the proximal end of the catheter shaft (fig. 1). Means for nebulizing the medicine discharged at the distal orifice into an aerosol plume of particles of the medicine can include the ventilator forcing air through the lumen. The catheter shaft is configured for placement in the patient's lungs (col. 3, lines 27-29). At least a portion of the catheter is constructed of a compliant material (col. 2, lines 16-18). As shown in figure 1, the catheter is capable of being bent back upon itself. Figure 1 shows the catheter in a generally U-shaped configuration. The catheter is clearly capable of being formed into a J-shape with a longer proximal portion and the J-shape being located at a more distal portion of the catheter. In this configuration the medicine is discharged in a direction toward the proximal end of the catheter shaft. This would appear to anticipate the claim language.

**Claims 69, 71-74, 99, 101-102, 106-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (5,031,613) in view of Makhoul et al. (5,291,882).**

Smith discloses a catheter (fig. 1) for delivering an aerosol of medicine to a patient comprising: a catheter shaft 2 having a proximal end and a distal end (fig. 1), the distal end 8 of the catheter shaft includes an hour-glass shaped neck 6 (fig. 2) configured to deliver the aerosol

plume of particles toward airway passage walls in a patient when the catheter is positioned in the patient (col. 3, lines 27-29); a lumen extending through the catheter shaft and adapted at a proximal end for receiving a medicine and communicating at the distal end with a distal medicine orifice from which the medicine is discharged in a direction toward the proximal end of the catheter shaft (fig. 1); and means for nebulizing the medicine discharged at the distal orifice into an aerosol plume of particles of the medicine (fig. 1); wherein the catheter shaft is configured for placement in the patient's lungs (col. 3, lines 27-29); wherein at least a portion of the catheter is constructed of a compliant material (col. 2, lines 16-18); wherein the medicine comprises a liquid (col. 3, lines 30-42); except for the distal end of the catheter shaft forms a J-shape. However, Makhoul et al. teaches a ventilation tube 14 that includes a distal end 28 having a J-shape (fig. 1), which serves to direct the flow of fluid away from the distal end (fig. 1, col. 5, lines 48-89). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the device in the Smith's reference, to include a catheter shaft having a J-shaped distal end, as suggested and taught by Makhoul, so that flow through the shaft is directed away from the distal of the shaft (fig. 1, col. 7, lines 43-50) toward the lungs.

#### ***Allowable Subject Matter***

Claims 91-97, 109-119 are allowed.

Claims 100, 81-90, 103 and 108 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Response to Arguments***

Applicant's arguments with respect to claims 69-74, 81-103, 106-119 have been considered but are moot in view of the new ground(s) of rejection.

Applicant has further defined the nebulized medicine as being discharged at the distal medicine orifice requiring further consideration and the new grounds of rejection.

Regarding the rejection of Smith et al. in view of Makhoul et al., applicant argues that the tube 18 of Makhoul is not curved or J-shaped. This is not the catheter that is J-shaped that has a lumen adapted for receiving medicine. Tube 14 is the equivalent catheter that contains the lumen for discharging the medicine. The catheter of Smith is the inner tube 2 that contains the lumen for injecting fluid in the ventilation path. The equivalent inner tube of Makhoul is tube 14 for injecting fluid into the ventilation path. Therefore one would look to the tube 14 of Makhoul as the equivalent structure which teaches the added benefit of directing the fluid in a direction toward the proximal end of the catheter. The rejection is not modifying the endotracheal tube to be J-shaped. It is modifying the catheter to be J-shaped, just as claimed.

It is also immaterial that tube 14 is part of the endotracheal tube 10. It is still a catheter because it is a hollow flexible tube for insertion into a body cavity or duct to allow passage of fluids.

Applicant argues that neither Smith or Makhoul teach a J-shaped distal end of a catheter. It is not clear how applicant can disregard the teaching of Makhoul. Makhoul clearly shows a J-shaped tube and lumen 14 in figure 2 for example.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danton DeMille whose telephone number is (571) 272-4974. The examiner can normally be reached on M-F from 8:30 to 6:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu, can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

31 March 2008

*/Danton DeMille/*  
Danton DeMille  
Primary Examiner  
Art Unit 3771